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Declarations under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW; ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

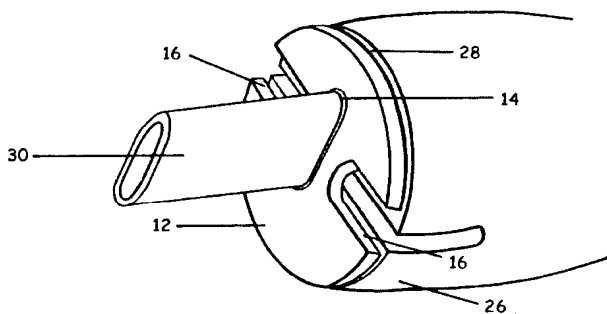
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SURGICAL STAPLING DEVICE AND METHOD



(57) Abstract: A surgical stapling device comprises an elongate housing (24) and a surgical staple slidable longitudinally within the housing towards a free forward end (28) thereof, the staple having a back and two forwardly pointing legs (22). The housing contains a staple-firing mechanism for driving the staple towards the free end of the housing, bending the staple to bring the free ends of the legs towards one another to close the staple, and releasing the closed staple. A cap (12) is located at the free end of the housing at a position where, in operation of the staple-firing mechanism, the cap becomes trapped between the back of the closed staple and human or animal tissue being stapled so as to provide a greater area of pressure on the tissue than in the absence of the cap.



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Surgical Stapling Device and Method

This invention relates to a surgical stapling device and method of surgical stapling.

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When performing catheterisation procedures, such as angiography or angioplasty, a catheter is generally introduced into the vascular system by first penetrating the skin, underlying tissues and blood vessel with a sharpened hollow needle. Next, a guidewire is commonly inserted through the lumen of the hollow needle and is caused to enter the selected blood vessel. Subsequently the needle is typically stripped off the guidewire and the combination of a dilator and/or introducer are fed over the guidewire and pushed through the skin to enter the blood vessel. The guidewire can then be removed and the desired catheter to carry out the procedure is fed through the lumen of the introducer and advanced through the vascular system until the working end of the catheter is appropriately positioned. Following the conclusion of the catheterisation procedure the working catheter will be withdrawn and subsequently the dilator and/or introducer will also be removed from the wound. Following this procedure the vessel puncture must be closed in order to prevent loss of blood through the puncture hole.

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Typically the wound is closed by maintaining external pressure over the vessel until the puncture naturally seals. This procedure can take approximately 30

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minutes with the length of time usually being greater if the patient is hypertensive or anticoagulated. The procedure can also be uncomfortable for the patient and involves costly professional time on the part of the hospital staff. Other pressure techniques such as pressure bandages, sand bags or clamps have been employed but these also involve ensuring the patient remains motionless for the extended period of time and is monitored to ensure the effectiveness of the procedure.

Therefore there is a need for a device which will close and seal the arterial puncture quickly and easily allowing the patient to become mobile within a short period of time, thereby increasing the throughput of patients in the catheterisation lab and increasing the availability of hospital staff for other duties.

Accordingly, the invention provides a surgical stapling device comprising an elongate housing, a surgical staple slidable longitudinally within the housing towards a free forward end thereof, the staple having a back and two forwardly pointing legs, a staple-firing mechanism for driving the staple towards the free end of the housing, bending the staple to bring the free ends of the legs towards one another to close the staple, and releasing the closed staple, the stapling device further including a cap located at the free end of the housing at a position where, in operation of the staple-firing mechanism, the cap becomes trapped between the back of the closed staple and human or animal tissue being stapled so as to provide a greater

area of pressure on the tissue than in the absence of the cap.

5 Preferably the device further includes an elongated locator member slidable longitudinally within the housing between an initial forward position wherein the locator member projects beyond the free end of the housing to enter a puncture site in a liquid-carrying vessel in a human or animal, thereby to locate the free
10 end of the housing at the puncture site, and a rearward position wherein the locator member is retracted into the housing in coordination with the closure of the staple, wherein the cap has a central opening which fits over the projecting locator member in its initial
15 forward position, the locator member being withdrawn from the central opening when it is retracted into the housing.

Most preferably the closure of the staple effects a
20 lateral compression of the cap to at least partially close the central opening.

The invention further provides a method of stapling human or animal tissue, the method including providing
25 a stapling device comprising an elongate housing, a surgical staple slidable longitudinally within the housing towards a free forward end thereof, the staple having a back and two forwardly pointing legs, and a staple-firing mechanism for driving the staple towards
30 the free end of the housing, bending the staple to bring the free ends of the legs towards one another to close the staple, and releasing the closed staple, the method further including placing a cap at the free end

of the housing and operating the staple-firing mechanism, the cap being located at a position where, in operation of the staple-firing mechanism, the cap becomes trapped between the back of the closed staple and human or animal tissue being stapled so as to provide a greater area of pressure on the tissue than in the absence of the cap.

A preferred embodiment of the invention to be described with reference to the drawings comprises a surgical stapling device as described in Irish Patent Application S2000/0722 in combination with a disk-like cap. The stapling device comprises a handle from which extends an elongated housing (shaft). At its end remote from the handle the shaft terminates in a bullet-like head from which, in an initial "pre-fire" position of the device, a locator tube extends a predetermined distance. A surgical staple with forwardly pointing legs is located wholly within the head of the shaft in the pre-fire position. A generally circular disk having a central opening is positioned over the locator tube concentric with and flush against the head of the shaft. The diameter of the disk is equal to or less than the diameter of the head of the shaft. On each side of the disk generally U-shaped slots are positioned to allow the staple legs to pass through the disk when they are advanced forward during deployment of the staple.

The locator tube locates the head of the shaft centrally over the puncture hole. On activation of the staple firing mechanism the staple is advanced forward so that the legs stab the vessel wall. As the firing

cycle continues the locator tube is retracted back into the head of the device and the staple legs are deformed through 90^0 in order to form a generally rectangular shape. Forming the staple causes the disk to become trapped between the staple back and vessel wall with additional lateral compression of the two side slots so as to close the central opening by which the disk was positioned on the locator tube.

10 The staple and cap combination has the effect of bringing the two sides of the central opening together and also creating a tamponade effect over an increased surface area so as to bring about haemostasis in a short time.

15 An embodiment of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of a staple and cap combination used in the present embodiment;

Fig. 2 is a perspective view of the head end of a surgical stapling device according to the present embodiment in a pre-fire position;

25 Fig. 3 is a side elevation of stapling device of Fig. 2 in the pre-fire position; and

Figs. 4(a) and 4(b), Figs. 5(a) and 5 (b), and Figs. 6(a) and 6(b) show successive stages in firing a staple into the wall of a blood vessel using the device of Fig. 2. in which Figs. 4(a), 5(a) and 6(a) are side

elevations of the device and Figs. 4(b), 5(b) and 6(b) are equivalent plan views of the staple and cap.

Fig. 1 shows a preferred surgical staple 10 and cap or cover 12 for use in the embodiment. The staple 10 is a generally U-shaped staple identical to that described in Irish Patent Application S2000/0722. The cap 12 is a generally circular flat deformable disk with a generally oval central opening 14 and two diametrically opposite generally U-shaped slots 16 extending radially inwardly from the periphery of the disk. The dimensions of the oval opening 14 are substantially the same as the external dimensions of an oval cross-section blood locator tube 30 (Fig. 2), and the major axis of the oval opening 14 is substantially normal to the direction of closure of the staple legs 22.

The disk 12 is constructed from a soft malleable biocompatible metal such as Titanium or a semi-flexible material such as Dacron, Hydrogel, Collagen or Cellulose, or other biocompatible material such as PLA, PGA or PLGA. When the staple 10 is positioned against the disk 12 in use, the hump 18 in the back 20 of the staple is aligned with one half of the oval opening 14 and the staple legs 22 project through the slots 16.

Fig. 2 shows a surgical stapling device according to the embodiment of the invention in its "pre-fire" position. Apart from the presence of the disk 12, the device may be identical to that described in Irish Patent Application S2000/0722, from which full details may be obtained. Briefly, however, the device comprises an elongate housing or shaft 24 extending

from a pistol-grip type handle (not shown) and terminating in a bullet-like head 26. The staple 10 is slidable longitudinally within the head 26, towards the free forward end 28 of the shaft 24, on a blood locator tube 30 slidable longitudinally within, and initially projecting forwardly beyond, the shaft. The legs 22 of the staple point forwardly. In operation, a trigger on the handle operates a staple-firing mechanism (not shown) within the shaft 24 which drives the staple 10 towards the free end 28, bends the staple to bring the free ends of the legs 22 towards one another to close the staple, and finally releases the closed staple. During this process the blood locator tube 30 is retracted into the housing in coordination with the closure of the staple.

According to the embodiment, the stapling device further includes the disk 12 which is located against the free end 28 of the shaft 24 at a position where, in operation of the staple-firing mechanism, the disk becomes trapped between the humped back 20 of the closed staple and the human or animal tissue being stapled so as to provide a greater area of pressure on the tissue than would be provided by the back 20 of the staple alone.

In particular, in the "pre-fire" position of the device, the locator tube 30 extends through the oval opening 14 in the disk 12 and extends a pre-determined distance beyond the free end 28 of the shaft. The staple 10, while positioned further back in the head 26, is in the same general alignment with the disk as shown in Fig. 1. However, it is important that the

staple legs 22 are positioned back in the staple head behind the disk 12 and not protruding beyond the free end 28 of the staple head. Fig. 3 is a side elevational view of the stapler head shown in Fig. 2.

5 It can be seen that the staple 10 is positioned across the locator tube 30 and behind the disk 12 at a distance at least equivalent to the length of the staple legs 22.

10 The steps involved in firing the staple 10 and disk 12 are illustrated in Figs. 4 to 6.

First, Fig. 4(a), the stapler head 26 is tracked over a guidewire 32 through the percutaneous tract until the front end of the locator tube 30 enters a blood vessel 34 providing positive indication that the free end 28 of the shaft 24 is sitting on the outer surface of the vessel adjacent the puncture hole 36 with the staple and disk positioned centrally across the puncture hole
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20 (see also Fig. 4(b)).

Now the staple-firing mechanism is operated to drive the staple forwardly such that the staple legs 22 puncture the wall of the vessel 34, Fig. 5(a). At
25 this point the locator tube 30 is also being retracted back into the staple head 26.

Continued operation of the staple-firing mechanism now causes the outer portions of the staple back 20 (i.e. the portions on either side of the hump 18) and the legs 22 to bend through approximately 90° towards one another and close the staple 10 to a generally rectangular configuration. Fig. 6(a). At this point

the staple 10 is compressing the cap 12 against the outer surface of the vessel wall thereby closing the puncture hole 36. During the final steps in the deployment process it is important to substantially close the oval opening 14 in the cap to prevent blood from leaking once the staple and cap are deployed. Thus, as seen in Fig. 6(b), as the staple back 20 is deformed, causing the staple legs 22 to arc through 90° , the opposite edges of the disk 12 are compressed inwards causing the central oval opening 14 to close.

An alternative embodiment (not shown) of the disk 12 may, instead of the slots 16, have two diametrically opposite holes which do not extend to the edges of the disk 12. In use these holes are aligned with the staple legs 22 so that the latter project through the holes.

Furthermore, if the disk 12 is made of a resilient material the oval opening 14 may be replaced by a simple slit extending substantially normal to the direction of closure of the staple legs, the slit being resiliently forced apart by insertion of the blood locator tube 30 and closing automatically, by reason of the resilience of the disk, when the tube 30 is retracted. Such an arrangement will not rely on closure of the slit by compression by the staple as the latter is deformed.

The invention is not limited to the embodiments described herein which may be modified or varied without departing from the scope of the invention.

Claims

1. A surgical stapling device comprising an elongate housing, a surgical staple slidable longitudinally within the housing towards a free forward end thereof, the staple having a back and two forwardly pointing legs, a staple-firing mechanism for driving the staple towards the free end of the housing, bending the staple to bring the free ends of the legs towards one another to close the staple, and releasing the closed staple, the stapling device further including a cap located at the free end of the housing at a position where, in operation of the staple-firing mechanism, the cap becomes trapped between the back of the closed staple and human or animal tissue being stapled so as to provide a greater area of pressure on the tissue than in the absence of the cap.

2. A device as claimed in claim 1, wherein the free end of the housing has a circular cross-section and the cap is generally in the form of a disk positioned substantially concentrically relative to the free end.

3. A device as claimed in claim 2, wherein the disk has two diametrically opposite apertures for accommodating the legs of the staple.

4. A device as claimed in claim 3, wherein the apertures comprise slots extending radially inwards from the periphery of the disk.

5. A device as claimed in any preceding claim, further including an elongated locator member slidable

longitudinally within the housing between an initial forward position wherein the locator member projects beyond the free end of the housing to enter a puncture site in a liquid-carrying vessel in a human or animal, 5 thereby to locate the free end of the housing at the puncture site, and a rearward position wherein the locator member is retracted into the housing in coordination with the closure of the staple, wherein the cap has a central opening which fits over the 10 projecting locator member in its initial forward position, the locator member being withdrawn from the central opening when it is retracted into the housing.

6. A device as claimed in claim 5, wherein the disk 15 is made of a resilient material and the central opening is a slit extending substantially normal to the direction of closure of the staple legs, the slit being resiliently forced apart by insertion of the blood locator tube and closing automatically, through the 20 resilience of the disk, when the blood locator tube is retracted.

7. A device as claimed in claim 5, wherein the central opening is generally oval with its major axis 25 substantially normal to the direction of closure of the staple legs.

8. A device as claimed in claim 7, wherein the closure of the staple effects a lateral compression of 30 the cap to at least partially close the central opening.

9. A method of stapling human or animal tissue, the method including providing a stapling device comprising an elongate housing, a surgical staple slidable longitudinally within the housing towards a free
5 forward end thereof, the staple having a back and two forwardly pointing legs, and a staple-firing mechanism for driving the staple towards the free end of the housing, bending the staple to bring the free ends of the legs towards one another to close the staple, and
10 releasing the closed staple, the method further including placing a cap at the free end of the housing and operating the staple-firing mechanism, the cap being located at a position where, in operation of the staple-firing mechanism, the cap becomes trapped
15 between the back of the closed staple and human or animal tissue being stapled so as to provide a greater area of pressure on the tissue than in the absence of the cap.

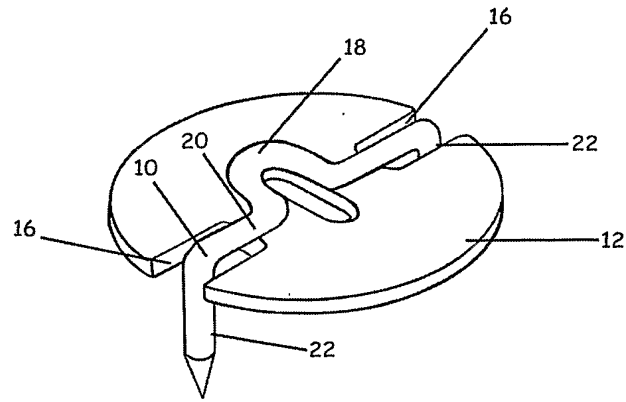


FIG. 1

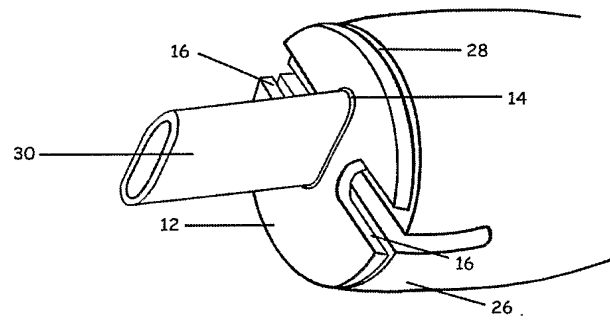


FIG. 2

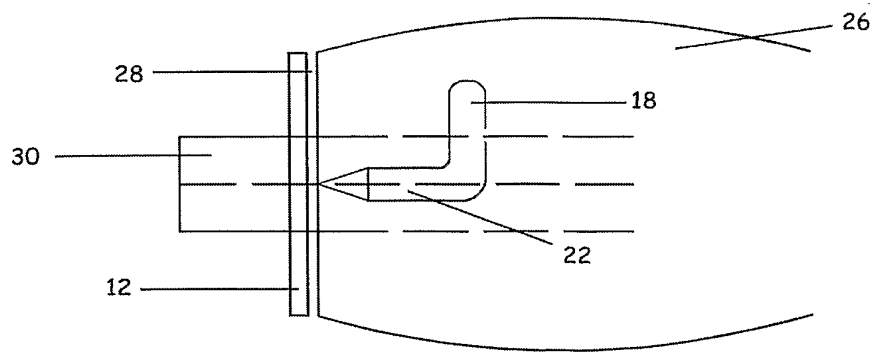
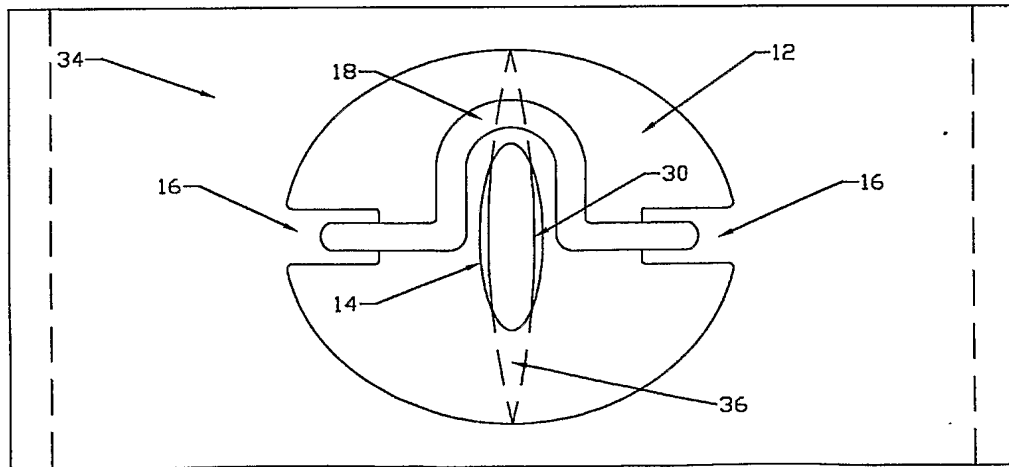
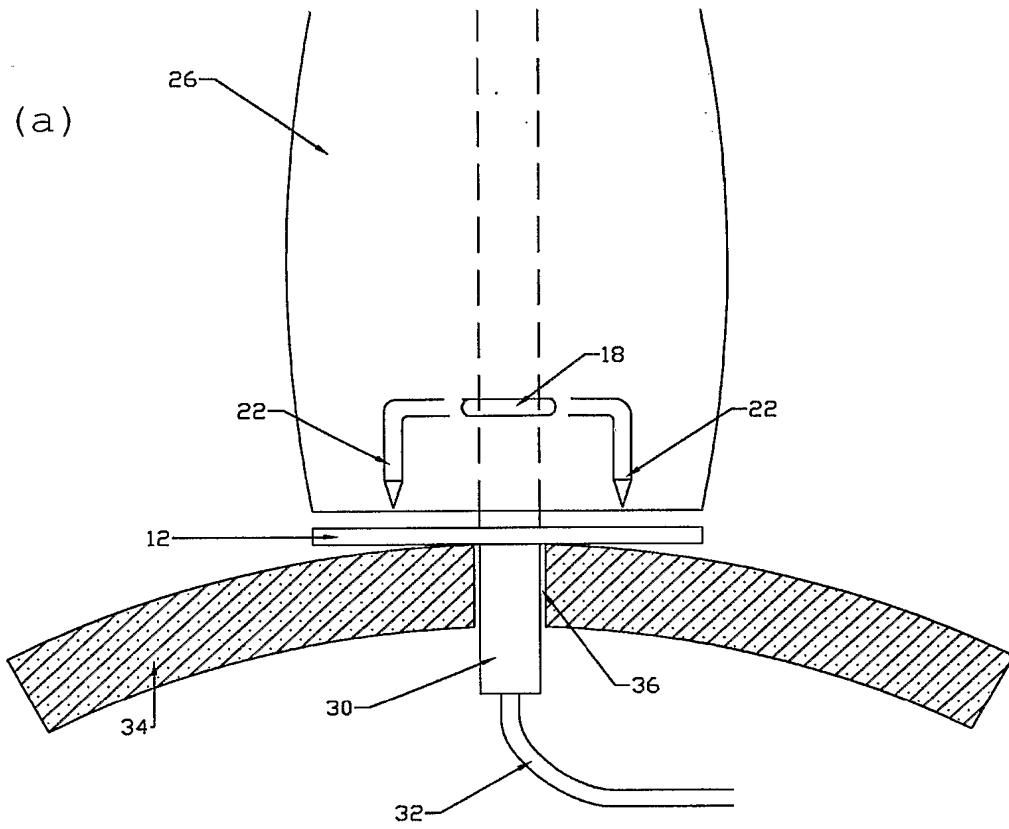


FIG. 3

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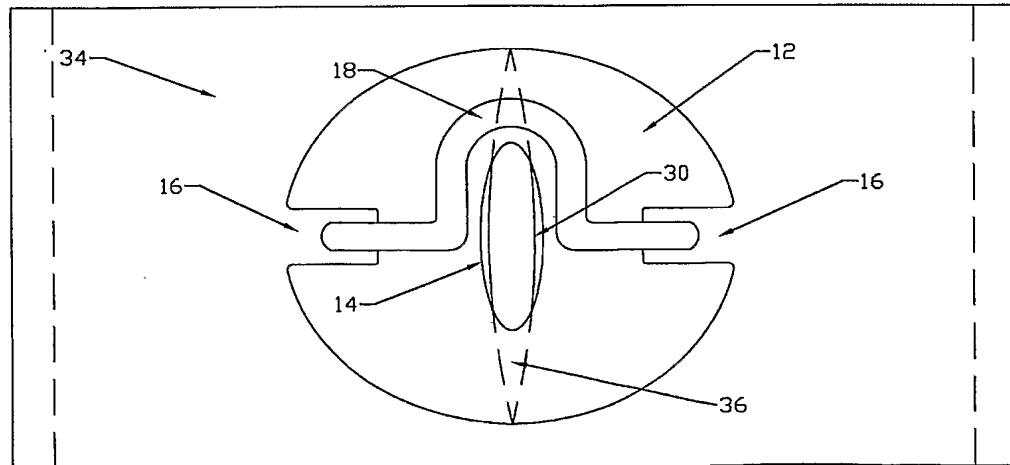
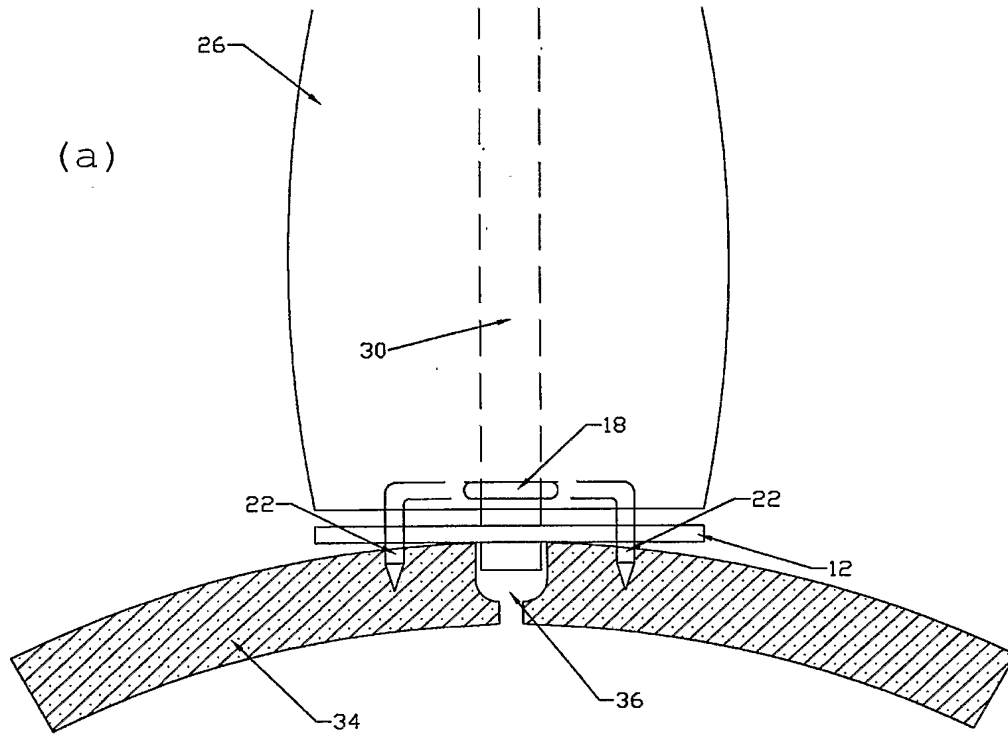
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FIG. 4



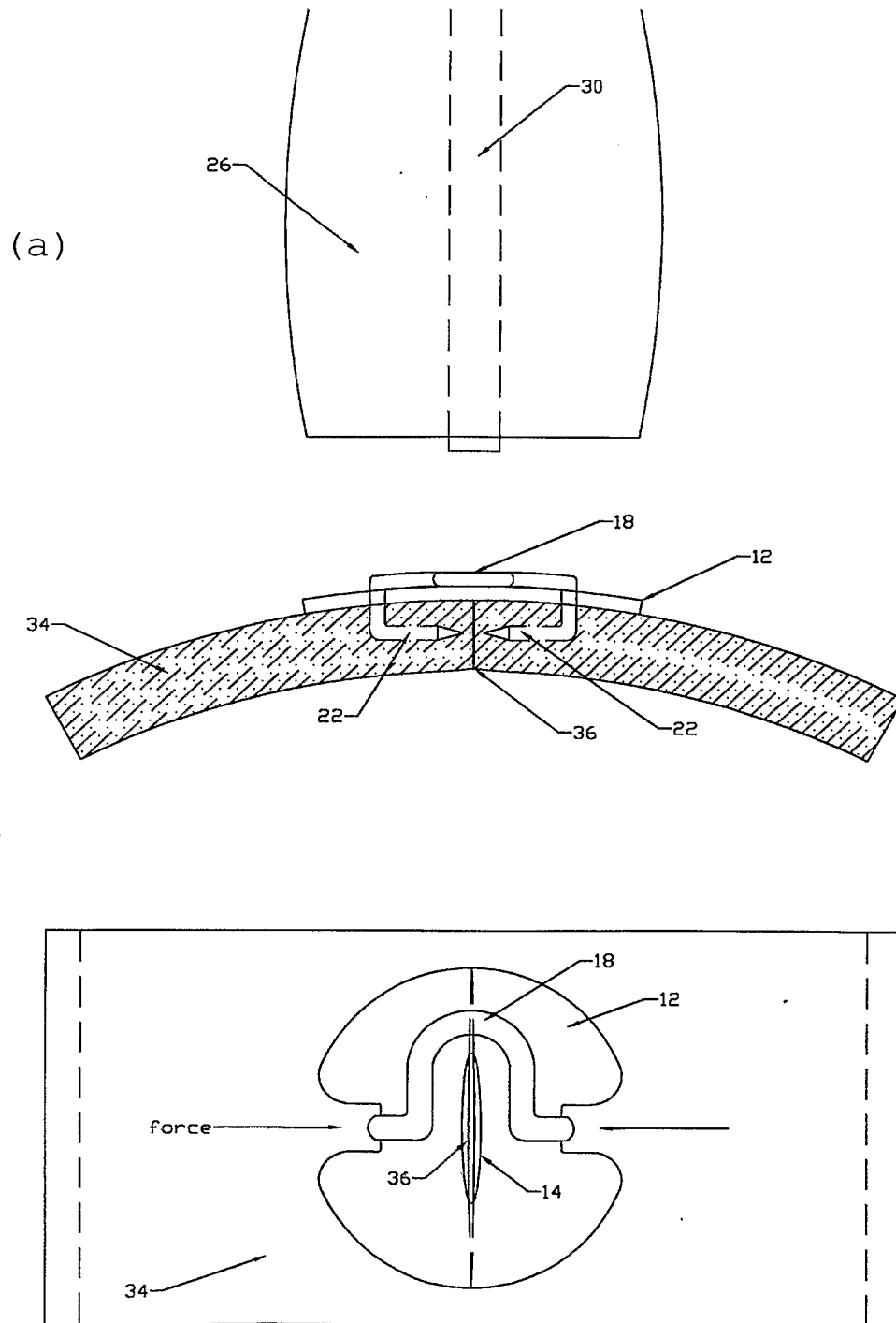
(b)

FIG. 5



(b)

FIG. 6



INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE 02/00118A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	ZA 200 100 527 A (MORRIS SEAN; ANTHONY THOMAS; COLEMAN JAMES E; CUMMINS CHRISTY; MARTIN C) 19 January 2001 (2001-01-19) cited in the application claim 1	1-8
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 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

° Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

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Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/IE 02/00118

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 9
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE 02/00118

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